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Applicants: Unger et al. Filed: October 30, 2000

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## REMARKS

## A. The Status of the Claims and the Amendments

By the present amendment, claim 67 has been amended to more particularly define the Applicants' invention and to claim it with greater specificity. New claims 68-81 have been added. The amendment to claim 67 and the subject matter claimed in new claims 68-81 are supported by the specification and the original claims. No new matter have been added.

After the present amendment has been entered, claims 3, 4, 6-17, 22-35, 61, and 63-81 will be pending, of which claims 12 and 13 have been previously withdrawn from consideration. It is submitted that the amendments place the claims in condition for allowance. Entry of the amendments is respectfully requested.

# B. Rejection Under 35 U.S.C. § 103(a)

Claims 3, 4, 6-11, 14, 17, 22-35, 61 and 63-65 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the published PCT patent application WO 96/40285 (Unger et al.) (item 4, pages 3-7 of the Office Action). This rejection is respectfully traversed on the following grounds.

It is well known that to support a *prima facie* case of obviousness over a reference, the following three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference as proposed by the Examiner; (2) there must be a reasonable expectation of success flowing from such a modification; and (3) the prior art reference, modified as proposed by the Examiner, must teach or suggest all of the claim limitations. MPEP § 2143. Applicants submit that the above criteria have not been met.

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Specifically, the Examiner has conceded (see, Office Action, page 5, lines 1-2 after the chart) that Unger et al. fail to explicitly disclose every element of claim 17, i.e., the use of a targeting ligand T (e.g., RGD) introduced into the claimed compound (IV) via a hydrophilic polymer (e.g., PEG) to be used with targeted vesicles comprising phosphatidylcholine and the claimed compound. The Examiner proposes to modify the

teachings of Unger et al. to arrive to what is claimed in claim 17.

The Applicants respectfully disagree that such a modification is permissible under the rules of establishing a prima facie case of obviousness. The Examiner's contention is that the overall disclosure of Unger et al. (e.g., page 61, claim 135) covers the compound of claim 17. The Applicants believe that the disclosure is not specific enough to provide the motivation to modify the teachings of Unger et al. in a way proposed by the Examiner. Very large number of compounds is indirectly disclosed in Unger et al., and to provide the needed motivation, more is needed than merely a generic mentioning of a class of compounds. The Applicants respectfully submit that one way of providing the motivation, in addition to the general disclosure, would be by providing some specific examples. However, the examples in Unger et al. are not directed to the compounds which will supply the requisite motivation.

Indeed, the embodiment of claim 17 shows that the compound to which the ligand T is attached via the polymer P is a diamide, wherein each of the two amide moieties is formed by a primary or secondary amino group and the acyl groups R<sup>1</sup> and R<sup>4</sup>. The acyl groups R<sup>1</sup> and R<sup>4</sup> are derived from fatty C<sub>16</sub>-C<sub>23</sub> acid(s). To contrast, a majority of compounds disclosed in Unger et al. (see, e.g., examples 1, 14, 47, etc.) include no amides, but rather include tertiary carbons substituted with groups other than amide groups. In other words, what is best exemplified in Unger et al. are compounds lacking amide groups; accordingly the examples in Unger et al. will not motivate to attach ligands to diamides.

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Accordingly, claim 17 is considered non-obvious in view of, and patentably distinguishable over, Unger et al. Each of claims 3, 4, 6-11, 14, 22-35, 61, and 63-65 directly or indirectly depends on claim 17, and is patentably allowable for at least the same reason. Reconsideration and withdrawal of the rejection of claims under 35 U.S.C. §103(a) are, therefore, respectfully requested.

## C. New Claims

The Applicants have added new claims 68-81. These claims correspond to the pending claims 22-35, but unlike claims 22-35 each of which depends on claim 17, the newly added claims 68-81 depend, directly or indirectly, on claim 66. Claim 66 has been allowed. It is therefore submitted that new claims 68-81 are also allowable, at least by the virtue of their dependency.

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#### **CONCLUSION**

In view of the above amendments and remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any matters remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number given below so that a prompt disposition of this application can be achieved.

No fee is deemed to be due in connection with this response. However, if any fee is due, the Commissioner is hereby authorized to charge any other fees associated with the filing submitted herewith, or credit any overpayments to Deposit Account No. 07-1896.

Respectfully submitted,

Date: February 8, 2006

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